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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/695,649

10/27/2003

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020979-002310US

3982

20350 7590 04/25/2008
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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

04/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/695,649	Applicant(s) GIFFORD ET AL.	
	Examiner MICHAEL KAHELIN	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-24 is/are pending in the application.
- 4a) Of the above claim(s) 21, 23 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-20 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/14/2008 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner was unable to find support for the negative limitation, "non-distensible."

Any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. Any

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claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement (See MPEP 2173.05(i)).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 11, 15, 18, and 19 are rejected under 35 U.S.C. 102(a/e) as being anticipated by Krueger (US 6,193,648, hereinafter “Krueger”).

6. In regards to claim 11, Krueger discloses a method for treating congestive heart failure (col. 3, ln. 43) comprising placing a band having a first and second end with a gap around a beating heart (Fig. 6) and drawing the first and second ends of the band together with a supporting spring member that spans the gap (30, 34, 32, and 35).

Please note that the “supporting spring member” is being interpreted as the entire suture/spring assembly.

7. In regards to claim 15, the drawing of the ends is delayed for a pre-selected time after placing the band (the time selected by the surgeon between the states depicted in Figures 6 and 7).

8. In regards to claims 18 and 19, the band is introduced to the heart and at least a portion of the band is below the AV groove (Fig. 6).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 16, 17, 20 and 22 are rejected under 35 U.S.C. 103(a) as obvious over Krueger. Krueger discloses the essential features of the claimed invention, including treating valvular disorders (abstract), but does not expressly disclose delaying drawing

of the band by holding the band apart with a biodegradable element, implanting with a subxiphoid approach or that the valvular disorder is mitral regurgitation. It is well known in the art to delay drawing of cardiac support bands by holding the band apart with a biodegradable element to provide the predictable results of allowing the band to be placed before constriction begins, to implant similar devices via a subxiphoid approach to provide the predictable results of implanting the device without the need to spread the chest, and treat such valvular disorders as mitral regurgitation with bands such as Krueger's to provide the predictable result of constricting the heart in such a way as to avoid this undesired regurgitation of blood. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Krueger's invention by delaying drawing of the cardiac support band by holding the band apart with a biodegradable element to provide the predictable results of allowing the band to be placed before constriction begins, implanting via a subxiphoid approach to provide the predictable results of implanting the device without the need to spread the chest, and treating such valvular disorders as mitral regurgitation to provide the predictable result of constricting the heart in such a way as to avoid this undesired regurgitation of blood.

12. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krueger in view of McCarthy et al. (US 6,406,420, hereinafter "McCarthy"). Krueger discloses the essential features of the claimed invention except for ends located on and adhered to opposite sides of an infarcted region, and a non-distensible band. McCarthy teaches a band device comprising ends located on opposite sides of an infarcted region

(col. 6, ll. 39-63) to provide the predictable results of promoting reverse remodeling of this compromised tissue, and a non-distensible restraint element (col. 7, ll. 38-47 and element 60) to provide the predictable results of rigidly supporting heart tissue to promote reverse remodeling. Further, it is well known in the art to provide cardiac reinforcement bands adhered to the heart to provide the predictable result of preventing the jacket from shifting during therapy. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Krueger's invention by providing ends located on opposite sides of an infarcted region to provide the predictable results of promoting reverse remodeling of this compromised tissue, and a non-distensible band to provide the predictable results of rigidly supporting heart tissue to promote reverse remodeling, and a band adhered to the heart to provide the predictable result of preventing the jacket from shifting during therapy.

Response to Arguments

13. Applicant's arguments with respect to claims 11-20 and 22 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Shapland (US 6,425,856) is an example of a compressive band held open by a biodegradable element, Chin (US 7,214,180) is an example of

subxiphoid implantation, and Walsh (US 6,902,522) is an example of a reinforcement jacket adhered to the heart.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Michael Kahelin/
Examiner, Art Unit 3762